RANDALL M. PENNER (State Bar No. 101201)
PENNER, BRADLEY & BUETTNER
1171 West Shaw Avenue, Suite 102
Fresno, California 93711
Phone: (559) 221-2100
Fax: (559) 221-2101

JAMES C. BARBER (State Bar No. 01706000)
Law Offices of James C. Barber (*Pro Hac Vice*)
4310 Gaston Avenue
Dallas, Texas 75246
Phone: (214) 821-8840
Fax: (214) 821-3834

Attorneys for Plaintiffs AUGUSTINE GAETA, individually, and MARGARITA GAETA, individually, and as Guardian Ad Litem for A.G., a minor child.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

AUGUSTINE GAETA, individually, and MARGARITA GAETA, individually and as Guardian Ad Litem for A.G., a minor child, Plaintiffs, v. PERRIGO PHARMACEUTICALS COMPANY; LONGS DRUG STORES CORPORATION, PAR PHARMACEUTICAL COMPANIES, INC., PAR PHARMACEUTICAL, INC., and BASF Corporation, Defendants.	CASE NO: 05-cv-04115-JW **PLAINTIFFS' SECOND AMENDED COMPLAINT**

TO THE HONORABLE UNITED STATES DISTRICT JUDGE:

Defendants having stipulated and the Court having granted leave, NOW COME plaintiffs, Augustine Gaeta, individually, and Margarita Gaeta, individually and as Guardian ad litem for A.G., a minor child, and file Plaintiffs' Second Amended Complaint against defendants Perrigo Pharmaceuticals Company, Longs Drug Stores Corporation, Par Pharmaceutical Companies, Inc., Par Pharmaceuticals, Inc., and BASF Corporation, and would show the following:

I. PARTIES

1. Plaintiffs are citizens and residents of Madera County, California.

2. Defendant Longs Drug Stores Corporation ("Longs") is a corporation organized under and by virtue of the laws of the state of Maryland with a principal place of business in Contra Costa County, California, and has been served and has answered.

3. Defendant Perrigo Pharmaceuticals Company ("Perrigo") is a corporation organized under and by virtue of the laws of the state of Michigan, with a principal place of business in Allegan County, Michigan, and has been served and has answered.

4. Defendants Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (collectively "defendants Par Pharm.") are corporations organized under and by virtue of the laws of the state of Delaware, with a principal place of business in Rockland County, New York, and may be served by serving their agent for service, The Corporation: Dennis J. O'Connor, at Par Pharmaceutical Companies, Inc., located at One Ram Ridge Road, Spring Valley, NY 10977.

5. Defendant BASF is a corporation organized under and by virtue of the laws of the state of Delaware, with a principal place of business in Morris County, New Jersey, and may be served by serving its registered agent for service, the CT Corporation System, located at 818 West 7th Street, Los Angeles, CA 90017.

II. JURISDICTION AND VENUE

6. Jurisdiction and venue are proper in the United States District Court, Northern District of California, San Jose Division, under 28 U.S.C. § 1332, based on diversity of citizenship and an amount in controversy exceeding $75,000, because plaintiffs are each residents of the State of California and defendants are all residents of states other than California; and under 28 U.S.C. § 1391(a)(2), because a substantial part of the events or omissions giving rise to this claim occurred in Santa Clara County, California.

7. California courts have personal jurisdiction over all defendants because they conduct or conducted at all relevant times business throughout California, including this District and Division.

8. Specifically, defendant Longs is a corporation organized under and by virtue of the laws

of the state of Maryland, which is qualified to do business in California, and is doing business in Santa Clara County, California. California courts have personal jurisdiction over Longs because it conducts business throughout California, including this District and Division.

9. Defendant Perrigo is a corporation organized under and by virtue of the laws of the state of Michigan, with a principal place of business in Allegan County, Michigan, which is qualified to do business in California, and is doing business in Santa Clara County, California. California courts have personal jurisdiction over Perrigo because it conducts business throughout California, including this District and Division.

10. Defendants Par Pharm. are corporations organized under and by virtue of the laws of the state of Delaware, with a principal place of business in Rockland County, New York, both of which are qualified to do business in California, and are doing business in Santa Clara County, California. California courts have personal jurisdiction over defendants Par Pharm. because they conduct business throughout California, including this District and Division.

11. Defendant BASF is a corporation organized under and by virtue of the laws of the state of Delaware, with a principal place of business in Morris County New Jersey, which is qualified to do business in California, and is doing business in Santa Clara County, California. California courts have personal jurisdiction over defendant BASF because it conducts business throughout California, including this District and Division.

III. STATEMENT OF FACTS

12. Defendant BASF was at all relevant times in the business of designing, manufacturing, and marketing a prescription form of nonsteroidal anti-inflammatory analgesic drug (NSAID) called "BASF 400 mg ibuprofen USP," also known by the generic name "ibuprofen" (the drug at issue in this action[1]).

13. Defendant BASF was also at all relevant times in the business of designing and manufacturing another distinct prescription form of NSAID on behalf of defendants Par Pharm., another 400 mg ibuprofen drug identified as (NDC#49884-0777-05), which is also known by the

[1] References in this complaint to "the drug" are to all of the ibuprofen drugs at issue in this action collectively.

generic name "ibuprofen" (the drug at issue in this action).

14. Defendant BASF is primarily responsible for manufacturing and labeling the prescription ibuprofen drug called BASF 400 mg ibuprofen USP, which is sold to hospitals, including Children's Hospital of Central California where the minor plaintiff, A.G., received one dose of the drug. BASF is also primarily responsible for manufacturing for other companies the prescription generic 400 mg ibuprofen drug identified as (NDC#49884-0777-05), which it manufactured and labeled for defendants Par Pharm. BASF is in the business of designing, manufacturing, marketing, selling, and distributing on its own behalf the drug, BASF 400 mg ibuprofen USP, to users in California and throughout the United States through various hospitals. BASF is also in the business of manufacturing generic forms of prescription ibuprofen, including the 400 mg ibuprofen (NDC#49884-0777-05) for defendants Par Pharm., which are sold to pharmacies by other generic drug companies and which are ultimately distributed and sold to consumers, including the plaintiffs, in California and throughout the United States, in retail stores and pharmacies.

15. Defendants Par Pharm. were at all relevant times in the business of designing and marketing prescription 400 mg ibuprofen (NDC#49884-0777-05), also known by the generic name "ibuprofen" (the drug at issue in this action).

16. Defendants Par Pharm. are primarily responsible for marketing and distributing the 400 mg ibuprofen (NDC#49884-0777-05), which it ultimately distributes after its manufacture by defendant BASF, and sells the drug to consumers in California and throughout the United States, including to plaintiffs through their pharmacy.

17. Defendant Perrigo was at all relevant times in the business of designing, manufacturing, and marketing an over-the-counter (OTC) NSAID called Longs Profen IB, also known by the generic name "ibuprofen" (the drug at issue in this action).

18. Defendant Perrigo is primarily responsible for manufacturing and labeling Longs Profen IB, under the direction and control of defendant Longs, pursuant to a contract manufacturing agreement. Perrigo is in the business of designing, manufacturing, selling, and distributing the OTC ibuprofen drug called Longs Profen IB to consumers and users in California and throughout

the United States through various retailers, including defendant Longs retail stores and pharmacies. Longs distributed and sold the OTC drug to consumers in California, including to plaintiffs, in retail stores and pharmacies.

19. Defendants and each of them intended that the aforementioned ibuprofen drugs reach users or consumers like plaintiffs in the condition in which they originally sold and distributed them. Further, defendants and each of them put these different drugs into the stream of commerce without any alteration or modification by any entity, distributor, or retailer.

20. Additionally, at all relevant times the defendants and each of them either individually or collectively, manufactured, distributed, and marketed the aforementioned ibuprofen drugs to be sold to consumers in California and throughout the United States.

21. On or about June 3, 2004, the minor plaintiff, A.G., a ten-year-old male with no known drug allergies, was in a state of good health when he underwent a surgical procedure to remove two congenital melanocytic nevi from his shoulders at Children's Hospital of Central California. During this surgical procedure, he was administered the anesthetic halothane for a very short period of time. For post-operative pain, A.G. was administered BASF 400 mg ibuprofen USP, the ibuprofen drug that was designed, manufactured, marketed, and distributed by defendant BASF. Upon discharge from the hospital, his treating healthcare provider instructed that he was to continue ibuprofen for pain.

22. After discharge from the hospital, plaintiffs purchased the OTC ibuprofen drug called Longs Profen IB, and A.G. took this drug from June 3, 2004 through June 6, 2004. Sometime before June 11, 2004, A.G. developed a fever and appetite loss. His pediatrician evaluated him on June 11, 2004, where he complained of fever and dizziness. His physician prescribed 400 mg Motrin and instructed him to continue ibuprofen every 6 hours. Plaintiffs filled this prescription, but the local pharmacy substituted a generic form of ibuprofen, which was the 400 mg ibuprofen (NDC#49884-0777-05) manufactured by defendant BASF for marketing by defendants Par Pharm. Subsequently, A.G. developed progressive dehydration and appetite loss. He returned to see his physician on June 13, 2004, where he was found to be significantly dehydrated, jaundiced, and ataxic. He was referred to the emergency room at Children's Hospital of Central

California for septic shock.

23. Upon admission to Children's Hospital of Central California on June 13, 2004, it was recorded that A.G. developed a rash, hypotension, coagulopathy, hypoglycemia, transaminitis, acute liver dysfunction, and hepatorenal syndrome. His medication history revealed that he had been using ibuprofen and not acetaminophen. He was admitted briefly to the PICU where his work-up revealed extraordinarily elevated liver enzymes, with his AST and ALT at 11,304 and 6,757 respectively. All viral and congenital etiologies for his acute liver dysfunction were ruled out, including EB, CMV, and Hepatitis A, B, and C. Toxicology/therapeutic levels were measured for acetaminophen and were negative. In the early morning hours of June 14, 2004 A.G. was transferred to Lucille Salter Packard Children's Hospital at Stanford for possible liver transplant, renal insufficiency, Stage 2 hepatic encephalopathy with shock, and respiratory distress.

24. On June 14, 2004, A.G. was admitted with acute hepatic failure to the PICU at Lucille Packard, in Santa Clara County, California, and underwent dialysis for acute renal failure. He also underwent a liver biopsy, followed by orthotopic liver transplant on June 16, 2004. Pathology reported that his liver revealed massive hepatic necrosis, most likely drug mediated, as shown by eosinophilia detected in the biopsy. The physicians at Lucille Packard ruled out etiologies for his acute liver failure, including infections, malignancy, metabolic problems such as autoimmune hepatitis, and congenital causes. Several physicians stated that ibuprofen toxicity was a cause of his acute liver failure.

25. As a result of his acute liver failure, A.G. developed coagulopathy disorders that led to vascular compromise with embolic events and compromised perfusion to his bilateral upper and lower distal extremities. He developed several necrotic digits of his bilateral hands and feet. These digits became gangrenous, which eventually led to amputation of several fingers and toes.

26. A.G. was hospitalized at Lucille Packard from June 14, 2004 until Sept. 3, 2004 due to significant complications including multiple infections, cholestasis, renal dysfunction, abdominal wound from surgery, and severe depression. He underwent multiple debridements on his right hand, both feet, and his abdomen, and required several weeks of dialysis for renal failure

following surgery. He was stabilized and transferred to Children's Hospital at Central California for extensive rehabilitation.

27. On Sept. 3, 2004, A.G. was admitted to Children's Hospital of Central California for rehabilitation and treatment for his injuries resulting from liver failure. He developed severe hypertension, anemia, and pancytopenia and continued to be severely depressed requiring treatment with anti-anxiety and anti-depressant medications. He was slowly transitioned from NG feedings to oral feedings. He had multiple skin grafts and amputations to his thighs, ankles, feet, and the digits on his hands during this hospitalization.

28. A.G. had a graft from his abdomen from the left thigh on Sept. 15, 2004 and underwent amputation of his right distal finger and a foot debridement on Oct. 6, 2004. He also had skin grafts to the ankles and feet from the left thigh on Nov. 12, 2004. Four digits were amputated from his right foot and four from the left foot were partially amputated on Dec. 7, 2004. A bone scan performed on Dec. 20, 2004 showed suspected bilateral hilar and tarsal avascular necrosis. Throughout his hospitalization, A.G. also underwent OT and PT to learn how to walk following his toe amputations and required special splints to assist him to transfer and walk using wheelchair and crutches.

29. A.G. was hospitalized from Sept. 3, 2004 to Dec. 29, 2004, when he was discharged home with the use of a wheelchair and crutches to walk short distances. Since his discharge, A.G. continues to follow up routinely with nephrology, gastroenterology, and surgical clinics to preserve his remaining digits, which may ultimately be subject to amputation, and to monitor his liver function for transplant rejection, as well as for other rehabilitative purposes to assist him with daily living.

30. A.G. is permanently disabled from acute liver and renal failure, which required a liver transplant, and amputation of his toes, which are all injuries he sustained as a result of his ingestion of the defendants' ibuprofen drugs. He suffers from severe depression from the multiple amputations of his extremities and from his inability to function normally like other adolescents his age, and from anxiety and fear from the past amputations and the possibility of liver failure and amputations in the future.

31. Plaintiffs had no knowledge of any potential dangerous defect or condition in any of the defendants' ibuprofen drugs at the time A.G. used them, and certainly no knowledge that they could cause acute liver failure, renal failure, and necrotic extremities leading to amputations of A.G.'s fingers and toes secondary to his liver failure. Nor did defendants Par Pharm., BASF, Perrigo, or Longs warn in any of the materials distributed with their drugs, in the package inserts, or on the OTC Longs Profen IB box or bottle or in any of its advertising designed to reach the consumer, that these ibuprofen drugs could cause acute liver failure, renal failure, or necrotic extremities leading to amputations of A.G.'s fingers and toes secondary to his liver failure, or what to do if the early symptoms of liver dysfunction or renal insufficiency occur after ingesting defendants' ibuprofen drugs, including nausea, fatigue, lethargy, pruritis, jaundice, rash, dizziness, abdominal pain, or decreased urine output, and to discontinue these drugs if one or more of these symptoms appear.

32. Plaintiffs used the drugs in the manner intended and in accordance with instructions that each defendant included with its drug for use as pharmacologic treatment for A.G.'s pain or fever. As a result of using defendants' ibuprofen drugs, A.G. suffered serious, painful, and permanently disabling injuries, including permanent and severe liver injury requiring transplant, amputation of his toes and other painful necrotic digits, hypertension, severe depression, and permanent immobility from the loss of his fingers and toes. He has also suffered substantial physical injuries, impairment, and disfigurement and scarring from his injuries. As a result of the injuries that were caused by his ingestion of the defendants' ibuprofen drugs, A.G. will require extensive and permanent rehabilitative and medical care for the rest of his life. Defendants' actions and/or omissions, together and/or collectively, including defective design, marketing defect, breaches of express and implied warranties, negligence, and gross negligence were each and all a substantial factor in causing A.G.'s injuries.

IV. CAUSE OF ACTION AGAINST ALL DEFENDANTS

A. Defective Design

33. Plaintiffs adopt each of the allegations in the foregoing paragraphs by reference, as if set forth fully herein. Additionally, plaintiffs allege that defendants and each of them defectively

designed their drugs because the prescription or OTC ibuprofen drugs ingested by A.G. did not perform as safely as an ordinary consumer would have expected them to perform at the time that A.G. used the ibuprofen drugs BASF 400 mg ibuprofen USP, Longs Profen IB, and Par Pharmaceutical's 400 mg ibuprofen (NDC#49884-0777-05), which rendered them unreasonably dangerous to A.G. and other persons similarly situated. Plaintiffs at all times hereto used the product in a way that was reasonably foreseeable to each of these defendants, and did not misuse the product pursuant to the box, bottle, and labeling that accompanied the product.

34. In particular, all of the forms of ibuprofen A.G. ingested contained the racemic mixture of S+ and R- ibuprofen, rendering them more toxic that the alternative design well known to defendants called dexibuprofen, and more dangerous to certain persons, particularly children, than other non-propionic acid based NSAIDs or fever-reducing products.

35. Additionally, defendants Perrigo and Longs failed to adequately test the ibuprofen drug Longs Profen IB for OTC use in children before presenting it to the FDA for such use and before selling and distributing it to the general public, and/or failed to adequately and completely inform or warn of the risks of liver injury and renal failure associated with the use of OTC ibuprofen to treat children for pain or fever.

36. Additionally, defendants BASF and Par Pharm. failed to adequately test their prescription ibuprofen drugs for use in children before presenting them to the FDA for such use and before selling and distributing them to healthcare providers and/or pharmacies, and/or failed to adequately and completely inform or warn of the risks of liver injury and renal failure associated with the use of ibuprofen to treat children for pain or fever.

37. Additionally, defendants BASF and Par Pharm. failed to adequately inform healthcare providers and patients about the increased risk of liver injury their drugs pose to consumers and the general public, and to provide warnings and instructions to both physicians and consumers through written materials regarding the recognition of the early symptoms of acute liver or renal injury when using their products.

38. Additionally, a safer alternative design existed that would have prevented or significantly reduced the risk of A.G.'s injuries, without substantially impairing the drug's utility, *i.e.*,

dexibuprofen. Furthermore, this safer alternative design was economically and technologically feasible at the time the drug left defendants' control by the application of existing or reasonably achievable scientific knowledge. Finally, the drug's risk to children far outweighed its benefit, particularly considering that there were other drugs on the market and available to physicians to prescribe and for consumers to purchase OTC that were safer and equally effective in reducing fever and pain in children.

B. Marketing Defect

39. Plaintiffs adopt each of the allegations in the foregoing paragraphs by reference, as if set forth fully herein. Additionally, plaintiffs allege that defendants' drugs and each of them were also defective and unreasonably dangerous because there was no warning, or alternatively, no adequate warning, that consumption could result in acute liver failure, renal failure, or in any type of severe life-threatening condition, including septic shock, vascular compromise, or necrotic extremities.

40. The warnings and instructions that accompanied the defendants' drugs provided inadequate warning to the consumer and/or healthcare provider about the risk of acute liver failure, renal failure, or any type of severe life-threatening condition, including septic shock, vascular compromise, or necrotic extremities, the degree of the risk of these conditions, and about the risk of other serious reactions A.G. suffered that were associated with the use of ibuprofen drugs, including defendants' ibuprofen drugs, or what to do in the event a patient like A.G. suffered an adverse reaction to the drug, such as discontinuing the drug if early symptoms of liver or renal dysfunction develop.

41. Specifically, there was no adequate warning about acute liver failure or hepatorenal syndrome on the respective prescription package inserts and no warning at all on the box or bottle label for the OTC ibuprofen drug Longs Profen IB, even though defendants had known about the connection between the drug ibuprofen and this severe, potentially fatal reaction since the late 1980s. Additionally, there was no adequate warning that if early symptoms of acute liver dysfunction or renal insufficiency develop, the drug should be stopped immediately and medical care sought, because such symptoms could be symptoms of a life-threatening condition. Nor

was there any warning that there was a greater risk of such reactions in children and that there was a greater risk of acute liver failure if the drug was used in conjunction with other well known hepatotoxic drugs. Specifically, the defendants and each of them have failed to provide adequate contraindications, precautions, and warnings to healthcare providers and consumers, including plaintiffs, that there are increased risks of acute liver failure if ibuprofen is taken with other drugs or by itself. These marketing defects were the producing cause of the plaintiffs' permanent injuries and damages.

C. Breach of Express Warranty

42. Plaintiffs adopt each of the foregoing allegations in the foregoing paragraphs by reference, as if set forth fully herein. Additionally, plaintiffs allege that defendants and each of them made express warranties as to their drug's utility in treating fever and pain symptoms/conditions, without making clear the extreme danger associated with a toxic reaction to the drug.

43. The express warranties described were part of the basis of the bargain between plaintiffs and defendants. Their drugs were not of the quality or condition expressly warranted by the defendants' affirmations and defective in that the drug ibuprofen is inherently dangerous to users, particularly children, and therefore cannot be used in the manner intended without serious risk of physical injury or death to the user.

D. Breach of Implied Warranty

44. Plaintiffs adopt each of the foregoing allegations in the foregoing paragraphs by reference as if set forth fully herein. In addition, plaintiffs allege that defendants and each of them impliedly warranted to the public generally and to the plaintiffs specifically that the drug was of merchantable quality and was safe and fit for its intended purpose when used under ordinary circumstances and in an ordinary manner.

45. Defendants knew or had reason to know of the purposes for which plaintiffs purchased the drug; that plaintiffs were relying on defendants' skill and judgment to select and furnish a suitable drug; and that the drug in question was unfit for the purpose for which it was intended to be used.

E. Negligence and Gross Negligence

46. Plaintiffs adopt each of the foregoing allegations in the foregoing paragraphs by reference as if set forth fully herein. Additionally, plaintiffs allege that defendants and each of them had a duty to use reasonable care in labeling, packaging, marketing, selling, advertising, warning, and otherwise distributing the drug. Defendants breached this duty by deliberately placing their drugs on the market without warning the prescriber, user, or consumer that ingestion of the drug could result in acute liver failure, renal failure, septic shock, necrotic extremities, or death, even though: (a) they knew that there was a probable relationship between their ibuprofen drugs and acute liver failure and renal failure, and also knew that it was a serious, often fatal or life-threatening reaction; (b) they knew that the medical literature for years had shown a connection between these reactions and NSAIDs or ibuprofen; and (c) they also knew there had been reported severe cases of liver dysfunction and renal failure associated with ibuprofen in children.

47. Additionally, plaintiffs allege that defendants knew that the FDA had concluded that there was a causal relationship between NSAIDs, including ibuprofen, and acute liver failure and renal failure. They also knew that the published literature had established the increased risks of liver and renal failure associated with NSAIDs and ibuprofen and that there were cases of acute liver and renal failure associated with ibuprofen, but they did not report them to healthcare providers or the FDA and also misrepresented the true risks and incidence of liver and renal failure and other serious reports of liver and renal dysfunction associated with the drug, and failed to place a warning about these potentially fatal reactions on the labeling materials, box, or bottle label of their respective ibuprofen drugs.

Additionally, defendants failed to warn the plaintiffs to stop the drug immediately and seek medical attention if any early symptoms of acute liver and renal failure developed because of the danger that such symptoms could progress to multi-organ failure and death. These acts and omissions, separately or in combination, were negligence and gross negligence and were a producing cause of plaintiffs' permanent injuries and damages, including punitive damages, as set forth below.

48. Each and all of the foregoing acts or omissions by defendants and each of them, acting

separately and collectively, were a proximate and/or producing cause of the injuries and damages sustained by the plaintiffs herein.

F. Deceit by Concealment—Cal. Civ. Code §§ 1709–10

49. Plaintiffs incorporate by reference each of the foregoing paragraphs as though set forth fully herein. Additionally, plaintiffs allege that defendants and each of them knew that the FDA had concluded that there was a causal relationship between NSAIDs, including ibuprofen, and acute liver failure and renal failure. They also knew that the published literature had established the increased risks of liver and renal failure associated with NSAIDs and ibuprofen and that there were cases of acute liver and renal failure associated with ibuprofen, but they did not report them to healthcare providers or the FDA and also misrepresented the true risks and incidence of liver and renal failure and other serious reports of liver and renal dysfunction associated with the drug, and failed to place a warning about these potentially fatal reactions on the labeling materials, box, or bottle label of their respective ibuprofen drugs.

50. Additionally, defendants knowingly made false and fraudulent representations in their marketing and advertising campaigns, including: (a) that their respective ibuprofen drugs were more effective than acetaminophen; (b) that their respective ibuprofen drugs had been adequately and reliably tested for use in the dosages recommended for children; and (c) that their respective ibuprofen drugs were safe for use by children in the recommended dosages.

51. Additionally, defendants possessed and continue to possess scientific data demonstrating that ibuprofen drugs, including their respective ibuprofen drugs, were linked to serious illness and potential fatal reactions, including acute liver failure and acute renal failure, but failed to warn about these serious and potentially fatal adverse reactions on the package insert, box, or bottle label of their respective ibuprofen drugs.

52. At all relevant times herein, defendants conducted sales and marketing campaigns to promote the sale of their respective ibuprofen drugs to willfully deceive A.G.'s physicians and the general public about the health risks and consequences of the use of these drugs. Defendants and each of them were aware that their respective ibuprofen drugs were not safe, fit, or effective for human consumption; that use of these drugs is hazardous to health; and that said drugs have

an unacceptable risk of serious injury and death to children, including the injuries A.G. suffered.

53. Further, defendants intentionally concealed and suppressed the facts concerning their respective ibuprofen drugs with the intent to defraud plaintiffs because the defendants knew that the plaintiffs or other consumers similarly situated would not purchase or use their drugs if fully aware of the facts concerning the drug.

V. DAMAGES

54. Plaintiffs incorporate by reference each of the foregoing paragraphs as if set forth fully herein. Plaintiffs seeks damage from defendants, jointly and severally, for the injuries and damages caused by use of the aforementioned drugs that were manufactured, marketed and sold by defendants in an amount in excess of the minimum jurisdictional limits of this Court. It is not possible for plaintiffs to plead the exact amount of these damages at this time, but they will plead it at a later time when it can be determined and as may be required by the rules.

55. Plaintiffs allege that the foregoing negligence and strict liability of defendants, acting separately and collectively, was a direct, proximate, and/or producing cause of the damages suffered by plaintiffs herein.

56. As a direct and proximate/producing result of the negligence and strict liability of defendants as set out above, minor plaintiff A.G. has suffered the following injuries and damages, among others, for which defendants are jointly and severally liable:

a. Physical impairment in the past and in reasonable probability such impairment will continue into the future;

b. Extensive medical and rehabilitation expenses for treatment of his injuries from age 18;

c. Severe physical pain and mental anguish caused by his injuries, treatment, and rehabilitation, which severe physical pain and mental anguish he will in all reasonable probability continue to suffer in this manner in the future;

d. Physical disability, including loss of his liver requiring liver transplant, loss of his fingers and toes and resulting physical impairment necessitating the use of a wheelchair for mobility, and post-operative wounds, scarring, and disfigurement

in the past, which physical disabilities and disfigurement he will in all reasonable probability continue to suffer in the future;

e. Permanent vocational impairment of his ability to obtain and perform any meaningful employment, rendering him totally and permanently disabled.

57. As a direct and proximate result of the negligence and strict liability of defendants as set forth above, Plaintiffs Augustine and Margarita Gaeta have suffered the following injuries and damages, among others, for which defendants are jointly and severally liable:

a. plaintiffs have been deprived of the care, society, companionship, maintenance and support of A.G.;

b. Extensive medical, rehabilitative, and attendant care expenses for A.G. to age 18.

VI. PUNITIVE DAMAGES

58. Plaintiffs incorporate by reference each of the foregoing paragraphs as if set forth fully herein. Defendants and each of them should be held liable for gross negligence and intentional misconduct as a result of their product liability, negligence, gross negligence, and intentional misrepresentation in: (a) manufacturing and placing into the stream of commerce a drug unsafe for its intended purpose; (b) failing to adequately warn the ultimate user and consumer of the inherent dangers in said drug; (c) failing to provide instructions for the safe use of said dangerous drug when defendants knew or should have known of the probable harm, injury, or death the drug could cause to the user; and (d) deliberately failing to warn about the danger of this potentially disastrous toxic reaction. Plaintiffs are therefore entitled to recover punitive and exemplary damages for defendants' gross negligence.

59. Plaintiffs also allege that each act of negligence by each and all defendants constituted individual and/or collective acts of gross negligence and/or fraud, oppression, or malice against plaintiffs. Specifically, plaintiffs adopt each of the allegations in paragraphs 8–53. These acts of negligence by each and all defendants involved an extreme degree of risk of harm to A.G. and constitute gross negligence that demonstrates conscious indifference to him.

60. Specifically, there was a high degree of risk of harm and death from acute liver failure and renal failure from the defendants' respective aforementioned ibuprofen drugs due to their

constituents. Yet defendants respectively proceeded with conscious indifference to A.G.'s safety and welfare; and/or alternatively, showed such actual conscious indifference to A.G.'s rights, welfare, and safety as to constitute fraud, oppression, or malice or gross negligence.

61. Plaintiffs are also entitled to prejudgment interest on said damages attributable to an ascertainable economic value pursuant to Cal. Civ. Code §§ 3288, 3291.

VII. JURY DEMAND

62. Plaintiffs respectfully request a trial by jury and have tendered the required jury fee with her First Amended Original Complaint.

WHEREFORE, plaintiffs pray that defendants be cited to appear and answer herein, that upon final hearing of this cause, plaintiffs have judgment against defendants for actual, punitive, and all other damages as provided by law, together with interest as provided by law and costs of court, attorney's fees, injunctive relief, and for such other and further relief, general and special, to which plaintiffs may be entitled, either at law or in equity.

Dated: February 28, 2006.

Respectfully submitted,	PENNER, BRADLEY & BUETTNER /s/ Randall M. Penner **RANDALL M. PENNER** PENNER, BRADLEY & BUETTNER 1171 W. Shaw Ave., Ste. 102 Fresno, California 93711 Phone: (559) 221-2100 Fax: (559) 221-2101 (State Bar No.101201) LAW OFFICES OF JAMES C. BARBER /s/ James C. Barber **JAMES C. BARBER** (*pro hac vice*) 4310 Gaston Ave. Dallas, Texas 75246 Phone: (214) 821-8840 Fax: (214) 821-3834 (State Bar No.01706000)